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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,859	12/17/2004	Kazuhiko Inoue	18493	5819
23389 7590 08/18/2009 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER LSTVOYB, GREGORY	
			ART UNIT 1796	PAPER NUMBER
			MAIL DATE 08/18/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,859

Applicant(s)

INOUE ET AL.

Examiner

GREGORY LISTVOYB

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43, 44, 49-54, 63-70, 77-131, 133 and 134 is/are pending in the application.
- 4a) Of the above claim(s) 77-130 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50, 67-70 and 134 is/are allowed.
- 6) ☐ Claim(s) 43, 44, 49, 51-54, 63-66, 131 and 133 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-44, 49, 51-54 and 63-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US patent 6018033) in view of Ruben (US 6146655) and further view of Helmus et al (US publication 2004/0093080 and WO 0154745) (all cited in the previous Office Action) (necessitated by Amendment)

Regarding Claims 43-44, 53 Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II-1 and 111-2 and Column 7, line 35).

Regarding Claim 52, Chen teaches a biodegradable resin can contain linear and branched structure (column 5, line 25).

Regarding Claim 51 Chen discloses cross-linked density in terms of Swelling Ratio. This ratio changes within a broad range of 5-90%. According to Flory, cross-link frequency can be calculated from the above parameter (more crosslink frequency corresponds with less swelling ratio). In examiner's opinion, Chen's composition internally possesses cross-linked density to meet the limitations of the above Claims.

Chen does not teach that his composition is moldable.

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

The advantage of Ruben is that the above gel can be molded in the shape of water-permeable porous envelope (see Abstract), which can be used in oral applications not only as drug delivery carrier, but also as reverse-osmotic membrane, effective for saliva removal (see column 9, line 60).

Therefore, it would have been obvious to a person of ordinary skills to use Chen's polysaccharides in moldable drug delivery compositions, since it allows increasing applicability of the material.

Regarding new limitation of claim 43, Chen or Ruben does not disclose a biodegradable resin based on polylactic acid.

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068). Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the same primary application as chen's one. Helmut teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130).

Helmus teaches that polysaccharides and polylactic acid can be equally used in thermoreversible gel compositions (see lines 0114 and 0116).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

It would have been obvious to a person of ordinary skills in the art to use a modified polylactic acid derivative in Chen's composition, since the esters, based on the above material are known material based on its suitability for its intended use.

Claims 131 and 133 rejected under 35 U.S.C. 103(a) as being unpatentable over Chen in view of Ruben and Helmus as applied to claims 43-44, 47-49, 51-57, 59-61 and 63-65 above and further view of Weissler et al (WO 2002/016378, cited with equivalent US 2004/0059101)

Chen discloses a modified Saccharide, Polyester, Polyalkylene Oxide (polyols) and Aminoacid based biodegradable thermo-reversible crosslinked resin, which is covalently bonded by Diels-Alder type linkage, which is cleaved at temperatures above 120C (Abstract, Column 6, line 35, Figures 1 and 12, Examples II-1, III-1 and III-2). A functional group can be dienyl, carboxyl, hydroxyl and others (Examples II-1 and III-2 and Column 7, line 35).

Ruben teaches moldable gel (used for drug delivery, which is the same application as Chen's one), which includes polysaccharides (see Abstract and Claim 1).

Helmus discloses a coatings in which the bioactive compound can be reversible (e.g., through a cleavable linker) to polylactic acid (Page 6, line 0068). Helmus teaches that the above copolymer can be used as a carrier for bioactive material (see line 0122). Note that Helmus's composition has the same primary application as chen's one. Helmut teaches that encapsulation of biologically active material can be performed in hot melt (see line 0130).

Helmus teaches that polysaccharides and polylactic acid can be equally used in thermoreversible gel compositions (see lines 0114 and 0116).

Chen or Ruben or Helmus does not teach cyclic dienes as Diels-Alder reagents.

Weissler teaches biodegradable reversible system (see line 0008), based on polysaccharide (see line 0011) and cyclic or acyclic diene (see line 0006). Weissler teaches that the above reagents produce a compound with well controlled structure and quantitative yield (see line 0008). Also, Weissler discloses that the reaction can be performed at mild conditions (see line 0008).

The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945) , 325 U.S. at 335, 65 USPQ at 301, see also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), *Ryco, Inc. v. Ag-Bag Corp.*, 857 F.2d 1418, 8 USPQ2d 1323 (Fed. Cir. 1988) and MPEP 2144.07.

Therefore, it would have been obvious to a person of ordinary skills in the art to interchangeably use cyclic and alicyclic dienes in Chen's composition, modified with Ruben, since these compounds are known material based on its suitability for its intended use.

Note that both Weissler and Chen apply their compound for drug delivery system and other medical purposes (see line Weissler, line 0002 and Chen, Col27, line 30).

Allowable Subject Matter

Claims 50, 67-70,134 allowed.

Response to Arguments

Applicant's arguments filed 5/13/2009 have been fully considered but they are not persuasive.

In the Office Action filed on 2/13/2009 Examiner indicated that Diels -Alder system based on polybutylene succinate (PBS) are not disclosed in the Prior Art.

In response, applicant added limitation with PBS-based Diels-alder system to the amended claim 43. However, Applicant also added polylactic acid as an alternative option to PBS to the same amended claim 43. As Examiner indicated in the previous Office Action, Diels Alder systems, which based on the polylactic acid are known in the Prior Art (see Helmus reference above) and thus are not patentable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James J. Seidleck/
Supervisory Patent Examiner, Art Unit 1796
GL